UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NEW YORK
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DIAPULSE CORPORATION OF AMERICA,

Plaintiff,

-against-

KATHLEEN SEBELIUS,[1] Secretary of Health and Human Services,

Defendant.
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REPORT AND RECOMMENDATION
06-CV-2226 (DLI)

GOLD, STEVEN M., U.S.M.J.:

Introduction

This case arises from the denial of plaintiff's claims for Supplementary Medical Insurance Benefits under Part B of the Medicare Act, Title XVIII of the Social Security Act, codified at 42 U.S.C. § 1395 *et seq.* Plaintiff is a provider of the Diapulse medical device and an assignee of patients' claims for Medicare benefits. Plaintiff was denied Medicare reimbursement for 188 claims related to its device, which "emits pulsed, high-frequency electromagnetic energy intended for the unattended treatment of open wounds and non-open wound injuries and medical conditions." Am. Compl. ¶ 9, Docket Entry 8. Plaintiff sought administrative review of the denial of payments, as provided by 42 U.S.C. § 1395ff(a) and its implementing regulations. Pursuant to 42 U.S.C. §§ 1395ff(b)(1) and 405(g), plaintiff now brings this action seeking judicial review of the final administrative decisions of defendant.[2]

[1] The caption has been altered to reflect the change in defendant's name. FED. R. CIV. P. 25(d).

[2] Plaintiff also alleged jurisdiction pursuant to 28 U.S.C. §§ 1331 and 1336 and the Administrative Procedure Act, 5 U.S.C. § 701 *et seq.* Am. Compl. ¶ 7. The Medicare Act, however, is the exclusive basis for jurisdiction. *See* 42 U.S.C. § 405(h) (providing that no action shall be brought under section 1331 to recover on a Medicare claim); *Heckler v. Ringer*, 466 U.S. 602, 622-24 (1984). Indeed, plaintiff concedes the jurisdictional issue and withdraws these other asserted bases for jurisdiction. Pl. Reply 1 n.1.

Both parties have moved for judgment on the pleadings pursuant to Federal Rule of Civil Procedure 12(c). The Honorable Dora L. Irizarry has referred the pending motions to me for report and recommendation. For the reasons stated below, I respectfully recommend that the Secretary's decision to deny payments be affirmed, with one exception.

Background

The Medicare Act

Title XVIII of the Social Security Act governs Medicare, the government health insurance program established to provide medical benefits to the elderly and disabled. Claims for Medicare benefits fall into two categories: Part A and Part B. Part A benefits are provided primarily for hospital and post-hospital expenditures, *see* 42 U.S.C. §§ 1395c - 1395i-5, while Part B benefits are supplementary, covering other medical expenditures including physician, diagnostic, and outpatient services and medical supplies, *see* 42 U.S.C. §§ 1395j, 1395k, 1395x. *See also* 42 C.F.R. Parts 407, 408, 410, 414 (regulations concerning Part B benefits).

The claims at issue here fall under Part B. As provided for in the Medicare Act, the Secretary of the Department of Health and Human Services delegates its administrative authority over Part B claims to one of its units, the Center for Medicare and Medicaid Services ("CMS"), which in turn authorizes private insurance carriers to administer Part B claims.[3] *See* 42 U.S.C. § 1395u(a); *Schweiker v. McClure*, 456 U.S. 188, 190-91 (1982). More specifically, the claims here were adjudicated by the Durable Medical Equipment Regional Carriers ("DMERCs") for Regions A, C, and D. The carriers are delegated the authority to make the initial determinations for reimbursement of Part B claims. 42 C.F.R. §§ 405.803, 421.200. In making any

[3] The various acronyms used throughout this Report are listed for convenience in Appendix A.

determination, the carriers are guided by the Medicare Act, and its implementing regulations, CMS rulings, the Medicare Claims Processing Manual ("MCPM"), Medicare Carriers Manual ("MCM"), any National Coverage Determinations ("NCDs"), and other policies, guidelines, and statements issued by CMS. *Id.* § 405.836. An NCD is a "determination by the Secretary with respect to whether or not a particular item or service is covered nationally" by Medicare. 42 U.S.C. § 1395ff(f)(1)(B); 42 C.F.R. § 405.1060(a)(1).

Medicare Part B Coverage

Medicare Part B reimburses providers and consumers only for those items and services that are "reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member." 42 U.S.C. § 1395y(a)(1)(A). The Secretary has the authority to determine what items and services are deemed "reasonable and necessary." *New York ex rel. Stein v. Sec'y of Health & Human Servs.*, 924 F.2d 431, 433 (2d Cir. 1991) (citing 42 U.S.C. § 1395ff(a)(1)). Even where a determination has been made that an item or service was not reasonable and necessary, the beneficiary may nonetheless be entitled to reimbursement if the individual and the provider did not know, and could not reasonably have been expected to know, that the item or service would not be covered. 42 U.S.C. § 1395pp(a); 42 C.F.R. § 411.406.[4]

Pertinent Medicare Policies

From 1995 to 2004, 188 claims for reimbursement of fees charged for home rental of plaintiff's device were denied. The decisions denying reimbursement are the subject of this lawsuit.

Several provisions of the MCM are implicated by plaintiff's application for

[4] This section is also referred to as the statutory waiver of liability or limitation of liability.

reimbursement. The Diapulse electromagnetic device at issue here qualifies as "durable medical equipment" ("DME"). 42 C.F.R. § 414.202. The MCM provides that a beneficiary may be reimbursed for the rental of DME if the following three conditions are met:

> A. The equipment meets the definition of DME (2100.1); and
> B. The equipment is necessary and reasonable for the treatment of the patient's illness or injury or to improve the functioning of his malformed body member (2100.2); and
> C. The equipment is used in the patient's home (2100.3).

Habermann Decision 7.[5] There is no dispute that the equipment at issue here meets the first and third criteria. Also pertinent to this case, the MCM states that

> Although an item may be classified as DME, it may not be covered in every instant. Coverage in a particular case is subject to the requirement that the equipment be necessary and reasonable for the treatment of an illness or injury, or to improve the functioning of a malformed body member. These considerations will bar payment for equipment which cannot reasonably be expected to perform a therapeutic function in an individual case . . . .

Id. The MCM further provides that a physician's prescription for the DME is generally sufficient to establish that the equipment is necessary. *Id.* at 7-8 (noting that MCM § 4105.2 requires a physician's prescription for reimbursement on a DME claim).

Over the years, CMS also issued several NCDs relevant to this case.[6] As noted earlier, an NCD is a coverage determination by the Secretary as to whether Medicare will pay claims for a particular item or service nationwide. 42 U.S.C. § 1395ff(f)(1)(B); 42 C.F.R. § 405.1060(a)(1). In 1997, CMS issued a non-coverage NCD, stating that Medicare would not cover electrical

[5] ALJ Habermann issued three decisions, the first dated May 26, 2004, the second dated June 22, 2004, and the third dated March 22, 2005. For convenience, "Habermann Decision" refers to the May 26, 2004 opinion, which can be found in the Administrative Record Volume ("R. Vol.") 13 at 336-73.

[6] A chronology of relevant events is set forth in Appendix B.

stimulation ("ES") DME for the treatment of wounds.[7] Def. Mem. App. B at 7 (2003 Decision Memo), Docket Entry 61-2 at 15. This NCD, however, was never put into effect because its implementation was enjoined as a result of a federal court challenge. *Id.* *See also Estate of Aitken v. Shalala*, 986 F. Supp. 57, 58 (D. Mass. 1997). Accordingly, claims for reimbursement for ES and electromagnetic therapy (such as Diapulse) continued to be determined on a case-by-case basis after *Aitken*. Def. Mem. App. B at 7.

In July 2002, after further review of its coverage policy, CMS announced a plan to issue a new NCD, effective April 1, 2003, that would allow limited coverage for ES for certain chronic wounds but specifically denied coverage for any electromagnetic therapy.[8] Def. Mem. 7; Def. Mem. App. B and C. In addition to limiting reimbursement for ES to treatment of chronic Stage III or Stage IV pressure ulcers, arterial ulcers, diabetic ulcers and venous stasis ulcers, CMS limited coverage to ES performed by a physician or physical therapist, or administered incident to a physician service.[9] Def. Mem. App. C (2003 NCD), Docket Entry 61-2 at 35. The proposed NCD explicitly denied coverage for the unsupervised use of ES, such as use by a patient treating himself in his home. *Id.* ("Unsupervised use of ES for wound therapy will not be covered, as this use has not been found to be medically reasonable and necessary.").

Diapulse thereafter requested review of the non-coverage policy. In response, CMS

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[7] "Electrical stimulation refers to the application of electrical current through electrodes placed directly on the skin in close proximity to the wound" and is thus distinguishable from, yet similar to, the Diapulse device, which uses electromagnetic therapy. 2003 Decision Memo at 14, Def. Mem. App. B. Prior to the issuance of the 1997 NCD, claims for ES (and electromagnetic therapy) were paid on a case-by-case basis. *Id.* at 6.

[8] In conjunction with the 2003 NCD, CMS established a new billing code for electromagnetic stimulation, E0761. Habermann Decision 22. CMS instructed DMERCs that they must automatically deny any claims using code E0761. *Id.*

[9] An ulcer is defined as an "open sore on the skin or on a mucous membrane." THE AM. MED. ASS'N, ENCYCLOPEDIA OF MEDICINE 1018 (Random House 1989).

issued a modified version of the NCD, effective July 1, 2004, allowing coverage for the use of electromagnetic therapy in treating wounds, but limiting coverage to the same extent as ES.[10] Def. Mem. App. D (2004 NCD, cited in CMS Medicare National Coverage Determinations Manual), Docket Entry 61-2 at 40 *et seq*. Thus, like the 2003 NCD, the new NCD provided that unsupervisesd use of ES or electromagnetic therapy would not be covered.[11] *Id.*, Docket Entry 61-2 at 41. *See also* 2003 Decision Memo, Def. Mem. App. B at 2 ("Electrical and electromagnetic stimulation for wound healing are not covered in the home setting, as unsupervised use by patients in the home has not been found to be medically reasonable and necessary."). The MCPM was modified to reflect the 2004 NCD and explicitly limits reimbursement to electromagnetic therapy *services* provided by a physician or other medical clinician. Def. Mem. App. E, Docket Entry 61-2 at 46 *et seq*. More specifically, it states that "Medicare will not cover the *device* used for the electromagnetic therapy for the treatment of wounds. However, Medicare will cover the service. Unsupervised home use of electromagnetic therapy will not be covered." *Id.* at 3, Docket Entry 61-2 at 48 (emphasis added).

Administrative Review of Part B Claims

Plaintiff sought review of the denials of its reimbursement claims in accordance with the administrative review process set forth in the Medicare Act and regulations. Medicare claims are

[10] The NCD does not bar payment for the use of the Diapulse device when used for purposes other than the treatment of wounds (for example, for the treatment of pain, edema, and swelling), but coverage for the treatment of these conditions continues to be made on a case-by-case basis by the carrier. Def. Mem. App. D; *see also* Nisnewitz Decision 6. "Nisnewitz Decision" refers to the September 7, 2005 opinion, which can be found in R. Vol. 2 at 703-14 and R. Vol. 3 at 881-92.

[11] Diapulse requested reconsideration of this NCD to permit coverage for home use. Nisnewitz Decision 10. Although the parties have not informed the court of CMS's decision, the CMS website indicates that the 2004 NCD is the current operative NCD concerning the treatment of wounds with ES and electromagnetic therapy. *See* Medicare National Coverage Determinations Manual, Chapter 1, Part 4, §§ 270.1 (2004 NCD) and 280.1 (DME NCD denying coverage for home use of ES), *available at http://www.cms.hhs.gov/manuals/downloads/ncd103c1_Part4.pdf.*

subject to a five-tier administrative review process. 42 C.F.R. Part 405, Subparts H, I.[12] After the submission of a claim for benefits, the Medicare carrier determines whether the services are valid and covered by Medicare, i.e., whether to pay or deny the claim. 42 U.S.C. § 1395ff(a); 42 C.F.R. §§ 405.803, 405.904, 405.920. A dissatisfied claimant may request review of a denied claim first by the carrier, and then by a carrier hearing officer if the amount in controversy is greater than $100. 42 U.S.C. § 1395ff(a)(3), (b)(1)(E)(i); 42 C.F.R. §§ 405.801, 405.807, 405.815, 405.817, 405.821. The Medicare carrier thus makes the first three coverage determinations. If the claim is greater than $500 and is rejected by the carrier hearing officer, a party may request review by an administrative law judge ("ALJ"), who will review the carrier decision *de novo*. 42 U.S.C. § 1395ff(b)(1); 42 C.F.R. §§ 405.801, 405.815, 405.855, 405.904, 405.1100, 405.1102. If still dissatisfied, a party may then appeal the ALJ's decision to the Medicare Appeals Council ("MAC"). 42 U.S.C. § 1395ff(b)(1); 42 C.F.R. §§ 405.815, 405.855, 405.904, 405.1100, 405.1102. The MAC's decision becomes the final decision of the Secretary. Lastly, if the denial of the claim is affirmed by the MAC and the amount in controversy is greater than $1,000, the party may seek judicial review. 42 U.S.C. § 405(g), §§ 1395ff(b)(1)(A), (b)(1)(E)(i); 42 C.F.R. §§ 405.801, 405.815, 405.857, 405.1130, 405.1136.

Administrative Review of Plaintiff's Claims

Two ALJs conducted *de novo* reviews of plaintiff's claims. The claims before ALJ Habermann were for the treatment of pain, swelling and edema caused by a variety of conditions, although the majority were for the treatment of post-operative pain and edema. *See* R. Vol. 18 at

[12] New rules took effect May 1, 2005. 70 Fed. Reg. 11420. At that time, Diapulse's claims were at the fourth and fifth level of the review process. Def. Mem. 3 n.1. The new rules did not affect Diapulse's case. *See* Def. Mem. 3 n.2 and 4 n.3.

2138-58 (Diapulse III decision, which includes claims that are the subject of Habermann's 2004 decision). The claims before ALJ Nisnewitz were for the treatment of open wounds, i.e., ulcers, and for the treatment of pain and edema. *See, e.g.*, R. Vol. 6 at 1528, 1755, 1818; R. Vol. 7 at 2045; R. Vol. 8 at 2260 (hearing officer decisions discussing the medical conditions at issue). Both ALJs affirmed the denial of plaintiff's claims in a total of six decisions.[13] In sum, ALJ Habermann and ALJ Nisnewitz determined that the Diapulse device was not reasonable and necessary when used by a patient at home. In addition, they both concluded that Diapulse was liable for the payments because it knew or should have known that the rental of the device would not be covered. In decisions dated March 15 and 16, 2006, the MAC denied plaintiff's appeal of the ALJ decisions. R. Vol. 12 at 1-7; R. Vol. 1 at 1-4.

1. ALJ Habermann's Decisions

Beginning in 1997, ALJ Habermann held numerous hearings concerning Diapulse claims and issued various decisions – some in favor of Diapulse and some against. Habermann Decision 2. In 1997 and 1999, he issued decisions holding that Diapulse was covered for the treatment of open wounds. *Id.* In 2000 and 2002, he held additional hearings to determine whether Diapulse was covered for the treatment of non-open wounds. *Id*. ALJ Habermann concluded that Diapulse was not reasonable and necessary as a treatment for non-open wounds. *Id.* Throughout

[13] As noted above, ALJ Habermann issued three decisions. Two of his decisions are identical but with different dates – the May 26 and June 22, 2004 decisions. *Compare* R. Vol. 13 at 336-88 *with* R. Vol. 12 at 278-332. His March 22, 2005 opinion reaches the same conclusion but addresses four claims that were omitted from his prior opinion because their files were lost. R. Vol. 12 at 31. ALJ Nisnewitz issued three nearly identical decisions – one dated September 7, 2005 and two dated September 8, 2005. ALJ Nisnewitz's September 7, 2005 decision involved forty-one claims appealing the denial of coverage by the DMERC for Region D. Nisnewitz Decision 2 n.3. As noted earlier, for convenience, "Nisnewitz Decision" refers to the September 7, 2005 opinion, R. Vol. 2 at 703-14 and R. Vol. 3 at 881-92. The September 8, 2005 decisions, beginning at R. Vol. 2 at 720, resolved the remaining twelve claims from two other DMERCs. *Id.*

In its complaint, plaintiff also sought review of a May 5, 2005 decision by ALJ Rayner, denying plaintiff reimbursement for home use of the Diapulse device by one beneficiary. Am. Compl. ¶¶ 23-30. The Diapulse device was used for the treatment of pain in June, 2004. Plaintiff does not address this claim in its motion and I recommend dismissing this claim either as abandoned or for the same reasons discussed with respect to the Nisnewitz decision.

this process, the MAC consolidated a number of cases before ALJ Habermann. *Id*. Finally, upon remand from the MAC, ALJ Habermann held hearings on November 13-14, 2003 and February 12-13, 2004 and then issued the three decisions that are the subject of judicial review here.

The claims before ALJ Habermann involved a total of 135 claims for Diapulse devices supplied to Medicare beneficiaries from 1995 through June, 2003. Habermann Decision Attachment A. These claims sought reimbursement for the rental of the Diapulse device by Medicare beneficiaries for use in their homes for the treatment of non-open wound conditions, such as pain, swelling, and edema. Am. Compl. ¶ 15. In his decision, ALJ Habermann indicated that the issue before him was "whether Diapulse therapy is covered for the treatment of injuries such as pain, swelling, and edema," and in particular whether the treatment is covered for home use. Habermann Decision 3. After compiling an extensive evidentiary record, ALJ Habermann concluded that Diapulse therapy may be reasonable and necessary for treatment of certain non-open wound conditions "but only in the supervised inpatient or outpatient clinic setting," and only if provided within the first forty-eight hours after surgery or acute injury. *Id.* at 38. In addition, he found that Diapulse should have known that its device would not be covered and therefore was not entitled to reimbursement pursuant to 42 U.S.C. § 1395pp(a). *Id*. at 36.

2. ALJ Nisnewitz's Decisions

The claims before ALJ Nisnewitz involved a total of 53 claims for reimbursement of the rental of the Diapulse electromagnetic device used by Medicare beneficiaries in their homes after April 1, 2003.[14] Nisnewitz Decision 2 n.3. ALJ Nisnewitz held a consolidated hearing on June

[14] The decision also includes three claims for continuous treatments that began prior to April 1, 2003 and continued thereafter.

20, 2005, which continued on September 1, 2005. *Id.* at 3. Relying heavily on the NCDs, ALJ Nisnewitz concluded that payment for rental of the Diapulse device was not covered by Medicare as a matter of general policy. *Id*. at 3-11. Like ALJ Habermann, ALJ Nisnewitz found that Diapulse knew or should have known that its device would not be covered and denied it reimbursement pursuant to 42 U.S.C. § 1395pp(a). *Id.* at 11.

Discussion

Standard of Review

In resolving a motion to dismiss, a court is generally limited to considering the factual allegations set forth in the pleadings. Here, the parties refer to the administrative record and ALJ decisions in the pleadings, and the parties have annexed these and other pertinent documents to their memoranda. Therefore, these documents are deemed incorporated in the pleadings and may properly be considered by the Court. *See, e.g., Allen v. Westpoint-Pepperell, Inc.*, 945 F.2d 40, 44 (2d Cir. 1991); *Kramer v. TimeWarner, Inc.*, 937 F.2d 767, 773-74 (2d Cir. 1991); *Fratellone v. Sebelius*, 2009 WL 2971751, at *6-7 (S.D.N.Y. Sept. 16, 2009) (permitting evidence outside of the administrative record which would assist the court in its review of the administrative record as it was presented to the Secretary).

A party is entitled to judgment on the pleadings only if it is clear that no material issues of fact remain to be resolved and that it is entitled to judgment as a matter of law. *See Juster Assocs. v. Rutland*, 901 F.2d 266, 269 (2d Cir. 1990). Neither party has identified any disputed material fact. Accordingly, the only question before the Court is whether either party is entitled to judgment as a matter of law.

The ALJs' conclusions of law are reviewed *de novo*. *Keefe v. Shalala*, 71 F.3d 1060, 1062 (2d Cir. 1995). An ALJ's "'failure to apply the correct legal principles is grounds for reversal.'"

Pollard v. Halter, 377 F.3d 183, 189 (2d Cir. 2004) (quoting *Townley v. Heckler*, 748 F.2d 109, 112 (2d Cir. 1984)).

Unlike conclusions of law, the Secretary's findings of fact in a final decision are to be upheld if they are supported by substantial evidence. *See* 42 U.S.C. § 405(g); *Keefe*, 71 F.3d at 1062. Substantial evidence is "more than a mere scintilla. It means such relevant evidence as a reasonable mind might accept as adequate to support a conclusion." *Richardson v. Perales*, 402 U.S. 389, 401 (1971); *see also Halloran v. Barnhart*, 362 F.3d 28, 31 (2d Cir. 2004). In determining whether the Secretary's decision is supported by substantial evidence, a "reviewing court must 'examine the entire record, including contradictory evidence and evidence from which conflicting inferences can be drawn.'" *Gheur v. Astrue*, 2008 WL 4469652, at *3 (E.D.N.Y. Sept. 30, 2008) (quoting *Brown v. Apfel*, 174 F.3d 59, 62 (2d Cir. 1999)); *see also Magee v. Astrue*, 2009 WL 464930, at *2 (S.D.N.Y. Feb. 25, 2009). Although the Medicare Act is to be liberally construed in favor of beneficiaries, plaintiff bears the burden of proving entitlement to Medicare benefits. *See Friedman v. Sec'y of Dep't of Health & Human Servs.*, 819 F.2d 42, 45 (2d Cir. 1987).

Plaintiff contends that the Administrative Procedures Act ("APA"), 5 U.S.C. § 551 *et seq.*, and its standard of review applies here. Pl. Mem. 9 *passim*, Docket Entry 63; Pl. Reply 2-3, Docket Entry 65. Under the APA, a court may overturn an agency decision if it is arbitrary, capricious, or an abuse of discretion. 5 U.S.C. § 706(2)(A). Plaintiff cites *Chipman v. Shalala*, 90 F.3d 421, 422 (10th Cir. 1996), and *Currier v. Thompson*, 369 F. Supp. 2d 65, 67 (D. Me. 2005), for the proposition that the APA standard may apply in a Medicare appeal arising under 42 U.S.C. § 1395ff(b), which explicitly provides for judicial review as set forth in § 405(g). Pl. Reply 2 n.2. *Chipman*, however, incorrectly relied on *Hennepin County Med. Ctr. v. Shalala*, 81 F.3d 741, 748

(8th Cir. 1996), which was a Medicare appeal arising under § 1395oo(f)(1). *Currier* in turn cited *Chipman*. Accordingly, the APA standard does not apply in this case, which is an appeal pursuant to § 1395ff, as indicated in paragraphs four to seven of plaintiff's amended complaint. *See also Estate of Morris v. Shalala*, 207 F.3d 744, 745 (5th Cir. 2000) (rejecting plaintiff's argument for application of the APA standard in an appeal under § 1395ff and thus distinguishing *Hennepin County*).

The Secretary argues that substantial evidence supports the ALJs' decisions. Def. Mem. 16-24. Plaintiff disputes that contention, and raises several additional grounds in support of its position that the decisions should be overturned. Some of these additional grounds challenge the ALJs' legal analysis, while others concern the factual evidence. More specifically, plaintiff argues that the ALJs' decisions should be reversed on the following legal grounds, which are subject to *de novo* review: 1) ALJ Habermann misapplied the burden of proof, 2) ALJ Habermann erred in qualifying as an expert Dr. Robert Hoover, the Medical Director of DMERC Region D, and in deferring to Dr. Hoover's conclusions, 3) both ALJs failed to consider relevant precedents, and 4) ALJ Nisnewitz improperly applied the 2003 NCD retroactively. Pl. Mem. 8-25. Plaintiff challenges the ALJs' factual findings and analysis leading to their conclusion that Diapulse therapy is not reasonable and necessary when used at home and that plaintiff knew or should have known its claims would not be covered. These findings are reviewed to determine whether substantial evidence supports them.

Plaintiff's Challenges to the ALJs' Decisions

ALJs Habermann and Nisnewitz issued thorough, detailed decisions that clearly explained their reasoning. I discern no legal error in their decisions. Moreover, I conclude that their decisions denying coverage are supported by substantial evidence. I find, however, that ALJ

Habermann has not explained the basis for his conclusion that Diapulse knew or should have known, throughout the pertinent period, that its claims would be denied, and I recommend a limited remand on that issue.

1. Applicable Burden of Proof

In his decision, ALJ Habermann explicitly stated that Diapulse had the burden of establishing the safety and effectiveness of its equipment. Habermann Decision 12.[15] Plaintiff argues that, once it established a *prima facie* case of entitlement to reimbursement, the burden shifted to the Secretary to establish an exception to payment pursuant to § 1395y(a)(1)(A). Pl. Mem. 9-11. This section provides that no payment may be made for items and services unless they are reasonable and necessary. Plaintiff's contention is without merit. In the Medicare reimbursement context, the burden remains with the claimant seeking reimbursement. *See Keefe*, 71 F.3d at 1062 ("Ultimately, however, the claimant bears the burden of proving her entitlement to Medicare coverage."); *see also Bolognese v. Sebelius*, 2009 WL 2223072, at *1 (2d Cir. July 27, 2009) (summary order). Although, as plaintiff contends, there may be burden-shifting from claimant to insurer in other contexts, plaintiff cites no authority holding that burden-shifting is appropriate when considering whether Medicare reimbursement should be denied on the basis that the item or service was not reasonable and necessary.

Plaintiff also contends that ALJ Habermann failed to apply the "treating physician rule." Pl. Mem. 10-11. Plaintiff argued to the ALJ that, consistent with the deference typically shown to treating doctors by Medicare and Social Security, a physician's signature on a Medicare claim not only establishes a *prima facie* case of medical necessity but is entitled to extra weight and deference. Plaintiff challenges the ALJ's decision rejecting this argument, a determination which

[15] ALJ Nisnewitz did not explicitly address the issue of burden of proof in his decision.

is reviewed here *de novo*. *See Keefe*, 71 F.3d at 1062.

The treating physician rule was developed by this Circuit in the context of Social Security disability cases. Under the rule as articulated by the Second Circuit, "[t]he treating source's opinion on the subject of medical disability . . . is (1) binding on the fact-finder unless contradicted by substantial evidence and (2) entitled to some extra weight, even if contradicted by substantial evidence, because the treating source is inherently more familiar with a claimant's medical condition than are other sources." *Schisler v. Bowen*, 851 F.2d 43, 47 (2d Cir. 1988) ("*Schisler II*"). The treating physician rule was eventually codified by the Secretary with respect to Social Security disability cases with certain changes. *See* Standards for Consultative Examinations and Existing Medical Evidence, 56 Fed. Reg. 36,932 (Aug. 1, 1991); *see also Schisler v. Sullivan*, 3 F.3d 563, 567-68 (2d Cir. 1993) (describing differences between codified and judicial rule).

The treating physician rule has never been extended to apply to Medicare coverage decisions. Prior to the codification of the rule, the Second Circuit had several opportunities to consider its applicability in Medicare cases, but has never read the rule so expansively. *See, e.g.*, *New York ex rel. Holland v. Sullivan*, 927 F.2d 57, 60 (2d Cir. 1991); *New York ex rel. Stein v. Sec'y of Health & Human Servs.*, 924 F.2d 431, 433-34 (2d Cir. 1991) (noting that "we believe it better practice to have the Secretary first advise us what role if any the attending physician rule played in the instant case and will play in future cases of this nature"); *Friedman*, 819 F.2d at 46. Plaintiff nonetheless urges application of the rule in this case, relying on the following passage from the Second Circuit's decision in *Holland*:

> we would expect the Secretary to place significant reliance on the informed opinion of a treating physician and either to apply the treating physician rule, with its component of "some extra weight" to be accorded to that opinion . . . or to supply a reasoned basis, in conformity with statutory purposes, for declining to do so.

927 F.2d at 60 (quoting *Schisler II*, 851 F.2d at 47) (internal citation omitted). *Holland* pre-dates the Secretary's codification of the rule, which applies only in disability cases. Moreover, it is obvious from the opinion that the court was merely speculating as to how the Secretary might formulate the rule if it were to be adopted, and not instructing courts reviewing denials of Medicare reimbursement claims to afford greater weight to the opinions of treating physicians. *See also Kaplan v. Leavitt*, 503 F. Supp. 2d 718, 723 (S.D.N.Y. 2007) (noting that only one court in the Second Circuit has applied the treating physician rule in the Medicare context). Accordingly, I find no legal error in the ALJ's refusal to apply the treating physician rule to Diapulse's claims.

2. Qualifying Hoover as an Expert

Next, I turn to whether ALJ Habermann committed legal error when he qualified Dr. Robert D. Hoover, the Medical Director of DMERC Region D, as an expert. ALJ Habermann sought the assistance of Dr. Hoover in understanding the scientific literature concerning Diapulse. Habermann Decision 28. Plaintiff concedes that it was not *per se* improper for the ALJ to solicit testimony from Dr. Hoover. Pl. Reply 5. Plaintiff objects, however, to ALJ Habermann's decision to qualify and rely upon Dr. Hoover in light of the fact that Dr. Hoover was the decision-maker who previously rejected plaintiff's claims for rental of the Diapulse device. Plaintiff argues that ALJ Habermann should have sought the assistance of a neutral medical expert, presumably meaning one who had not previously taken a position on whether Diapulse treatments are reasonable and necessary.

The federal regulations that set forth the procedures governing the hearings before ALJs are silent with respect to the appointment of experts. *See* 20 C.F.R. §§ 404.929-404.961.[16] The

[16] Although these regulations describe Social Security disability hearings, they are incorporated by reference in the Medicare regulations. *See* 42 C.F.R. § 405.801(c) ("Subparts J and R of 20 CFR part 404[, which includes

regulations, however, do provide that a hearing be open to anyone the ALJ deems "necessary and proper," 20 C.F.R. § 404.944, thus suggesting that the ALJ was acting well within his discretion when he sought the assistance of Dr. Hoover in understanding the scientific literature supporting Diapulse therapy. Nothing in the statutes or regulations expressly prohibits a Medical Director such as Dr. Hoover from testifying at a Medicare hearing.

Moreover, the ALJ's use of Dr. Hoover did not violate any fundamental principles of fairness. Plaintiff had a full opportunity to present its own medical expert testimony, to cross-examine Dr. Hoover and to offer rebuttal evidence. Habermann Decision 18-19, 22, 24. *See also* R. Vol. 2 at 658-83; R. Vol. 14 at 703; R. Vol. 16 at 1753, 1777 (letters from plaintiff responding to Dr. Hoover's letters); R. Vol. 31 at 6587-6633 (transcript of hearing before ALJ Habermann in which plaintiff questioned Dr. Hoover extensively concerning his opinions).

In addition, it appears that, while he originally denied plaintiff's claims for coverage in his capacity as Medical Director of DMERC Region D, Dr. Hoover reviewed plaintiff's evidence with an open mind. Upon further review of plaintiff's submissions to ALJ Habermann, Dr. Hoover changed his original opinion and stated that he would support coverage for Diapulse in the treatment of pain and edema when used under physician supervision during the first forty-eight hours after an injury. Habermann Decision 31; R. Vol. 16 at 1735 (letter of Dr. Hoover dated Jan. 26, 2004). *See also* R. Vol. 31 at 6687 (testimony of Dr. Hoover at hearing before ALJ Habermann in which he states that he reviews the question of coverage for the Diapulse device almost annually, if not more frequently).

Finally, as is clear from his written decision, ALJ Habermann did not simply adopt a

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§§ 404.900-404.999d,] are also applicable to ALJ, DAB, and judicial review conducted under [the Medicare Part B program]. . . .").

conclusory personal opinion asserted without explanation by Dr. Hoover. Rather, the aspects of Dr. Hoover's testimony relied upon by ALJ Habermann involved an analysis of the expert testimony and medical literature presented by plaintiff. Habermann Decision at 29-30. ALJ Habermann's decision explains, in substantial detail, the reasons for Dr. Hoover's skepticism about the testimony and literature supporting the use of Diapulse treatments, particularly for non-open wounds.[17] Thus, the decision demonstrates that the ALJ did not simply rest his conclusion on Dr. Hoover's opinion, but instead thoroughly considered the reasons for Dr. Hoover's skepticism and found them persuasive.

In its reply, plaintiff refines its argument and contends that, even if it was proper to call Dr. Hoover, it was error not to call any independent, neutral expert. Pl. Reply 5. The ALJ, however, is not required to call an independent expert at all, and thus his failure to do so was not error.

Plaintiff also contends that the MAC remand order required ALJ Habermann to consult a neutral expert and that ALJ Habermann failed to comply with the MAC's directive. Pl. Mem. 12-13. Plaintiff's argument is factually erroneous in two respects. First, the MAC remand order that plaintiff cites directed ALJ Habermann to obtain "medical expert testimony," and gave no instruction about from whom that testimony might properly be sought.[18] Pl. Mem. App 1 at 7-8, Docket Entry 63-2 at 8-9. Second, as outlined in ALJ Habermann's 2004 decision, the 1998 MAC remand plaintiff cites was issued on appeal from ALJ Habermann's Diapulse I decision, in

[17] These reasons are discussed in greater detail below, in the section of this Report discussing whether the ALJs' decisions were supported by substantial evidence.

[18] This 1998 MAC remand order also instructed the ALJ to obtain information from the DMERC and stated that he "may obtain testimony from . . . the DMERC medical director . . . as to whether the diapulse machine may in general be considered safe and effective and medically reasonable and necessary for treatment of the conditions at issue in the home." Pl. Mem. App. 1 at 6. Clearly, the MAC does not object to the use of DMERC medical directors as experts in administrative proceedings.

which ALJ Habermann held that Diapulse was safe and effective for treatment of wounds. Habermann Decision 2. After the 1998 MAC remand, ALJ Habermann held further hearings (it is not clear who, if anyone testified as an expert) but he concluded again in Diapulse II that Diapulse was covered for the treatment of wounds. *Id.* Thus, the 1998 MAC remand order directing the ALJ to consult a medical expert was issued in connection with an earlier hearing and was not intended to control the proceedings at issue here.

For these reasons, I find no legal error in the ALJ's qualification of and reliance on Dr. Hoover as an expert.

3. Precedential Effect of Prior Cases and FDA Clearance

Next, plaintiff contends that both ALJs Habermann and Nisnewitz erred in failing to give proper deference to other administrative decisions. Pl. Mem. 18, 25 (citing 20 C.F.R. § 422.203(c)). In support of its argument, plaintiff cites two administrative decisions in particular, *Matter of Hudson* and *Matter of Arbelo*, which it argues were precedential and should have been followed by the ALJs. *Id*.; Pl. Mem. App. 2 (*Matter of Arbelo*, decision dated Jan. 28, 2000); R. Vol. 2 at 855-72 (*Matter of Hudson*, decision dated Mar. 25, 2003).

Prior versions of the Code of Federal Regulations provided that "ALJs must follow 'appropriate precedents.'" 20 C.F.R. § 422.203(c) (2003 version).[19] No other regulation discusses the precedential effect of prior decisions and no regulation requires an ALJ to decide a claim in the same way as any other ALJ.

Additionally, subsequent to these earlier decisions in favor of coverage, the legal landscape changed with the issuance of the 2003 NCD mandating denial of coverage for Diapulse when used

[19] The current version omits this language and simply states that the ALJ must base his decision "on the preponderance of the evidence offered at the hearing or otherwise included in the record." 20 C.F.R. § 422.203(c).

in the home. *See also* Habermann Decision 3. Moreover, both *Hudson* and *Arbelo*, unlike the decisions at issue here, involved claims for the treatment of open wounds. Thus, the ALJs were not bound to follow these precedents when considering whether Diapulse is covered for the treatment of non-open wounds, i.e., pain, swelling and edema.

Plaintiff also cites *Hudson* and *Arbelo* in support of its argument that ALJ Habermann previously considered FDA approval of Diapulse equipment as one of several factors relevant to determining coverage, and held that the Diapulse device was covered. Pl. Mem. 18; *see* Pl. Mem. App. 2 (*Arbelo*); R. Vol. 2 at 868 (*Hudson*). Plaintiff seems to argue that these prior decisions required ALJ Habermann to consider FDA approval as a factor supporting coverage in connection with the determinations at issue here. These prior decisions, however, did not hold that FDA approval mandates Medicare coverage, and did not ascribe any specific weight to the fact of FDA approval. Moreover, case law and Medicare policy hold that FDA approval is not necessarily co-extensive with Medicare coverage. *See Svidler v. U.S. Dep't of Health & Human Servs.*, 2004 WL 2005781, at *5 (N.D. Cal. Sept. 8, 2004); 2003 Decision Memo, Def. Mem. App. B at 8 (noting that "a device must receive FDA approval or clearance for at least one indication to be eligible for Medicare coverage[, but] . . . . FDA approval/clearance alone does not entitle that device to coverage"). Accordingly, there was no error in failing to consider FDA approval when the ALJs determined that the Diapulse claims should be denied.

4. Retrospective Application of the NCD

Finally, plaintiff argues that ALJ Nisnewitz violated legal principles restricting retroactive application of new rules when he applied the 2003 NCD, which went into effect April 1, 2003, to claims for continuous courses of treatment that started prior to that date. Pl. Mem. 21-25. Plaintiff's argument, however, misconstrues the applicable law. The principle limiting

retroactive application of new rules is rooted in considerations of fairness – "individuals should have an opportunity to know what the law is and to conform their conduct accordingly." *Landgraf v. USI Film Products*, 511 U.S. 244, 265 (1994). However, a regulation "does not operate 'retrospectively' merely because it is applied in a case arising from conduct antedating the [regulation's] enactment, or upsets expectations based in prior law." *Id*. at 269 (internal citation omitted). The Supreme Court has held that, to determine whether a regulation has been given improper retrospective application, "the court must ask whether the new provision attaches new legal consequence to events *completed before its enactment*." *Id*. at 269-70 (emphasis added). Similarly, the applicable statute provides only that new rules, regulations and policy statements "shall not be applied (by extrapolation or otherwise) retroactively to items and services furnished before the effective date of the change," and does not provide for continued coverage even as part of an ongoing course of treatment, after the change becomes effective. 42 U.S.C. § 1395hh(e)(1)(A).

Here, neither ALJ held that the 2003 NCD required denial of claims for the rental of the Diapulse device prior to the NCD's effective date. Plaintiff's contention – that once a course of treatment begins and is covered, coverage must continue – goes well beyond the principle stated in *Landgraf* or codified in § 1395hh. Plaintiff's position is illogical; taken to its extreme, plaintiff's position would support coverage for a prescription drug taken by a patient for a chronic condition, once thought to be safe and effective for that purpose, even after new research demonstrated the drug to be ineffective or even dangerous. Moreover, plaintiff had fair notice prior to the effective date of the 2003 NCD – based on the 2002 decisional memo – that electromagnetic therapy in general and any use of the Diapulse device in the home would not be covered.

Finally, Diapulse had no vested or automatic "right" to reimbursement, even prior to the

issuance of the 2003 NCD; before the NCD was issued, Diapulse coverage decisions were made on a case-by-case basis. For these reasons, it was not error to consider the 2003 NCD with respect to claims for treatments that took place after the NCD was issued, even if those treatments were part of a continuing course of therapy that began prior to the issuance of the NCD. *See also* Nisnewitz Decision 7 (noting that there was no "protected status" for treatment that began prior to the NCD).

In sum, I find no legal error in either of the ALJs' decisions.

Whether Substantial Evidence Supports the ALJs' Decisions

As noted above, the ALJs' decisions should be affirmed if substantial evidence supports them. The weight accorded to any particular evidence is clearly within the purview of the ALJ and is not properly examined on judicial review. *See Fratellone v. Sebelius*, 2009 WL 2971751, at *9 (S.D.N.Y. Sept. 16, 2009) (noting that a court should not re-weigh the evidence).

Medicare carriers may reimburse providers and consumers only for those services that are "reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member." 42 U.S.C. § 1395y(a)(1)(A). Typically, to be covered by Medicare, a service or device must be "safe, demonstrated as effective, generally accepted in the medical community, and appropriate." *Aitken*, 986 F. Supp. at 59 (internal quotation marks omitted). Both ALJs determined that plaintiff failed to demonstrate that Diapulse was reasonable and necessary when used by an individual at home. Accordingly, I review the administrative record for evidence of whether Diapulse was safe and effective when used in the home and whether such use is generally accepted in the medical community.

A review of the evidence presented in the administrative proceedings reveals that plaintiff failed to meet its burden. To the contrary, the record contains substantial evidence supporting the

conclusions reached by the ALJs.

1. ALJ Habermann's Decision

Despite the volume of the evidence offered by plaintiff in support of its claims, the record, viewed as a whole, also contains substantial evidence, set forth by ALJ Habermann in thorough detail, supporting the conclusion that the use of Diapulse in the home for the treatment of pain, swelling and edema has not been shown to be safe and effective. As noted above, ALJ Habermann relied heavily on Dr. Hoover's review of the voluminous scientific literature and of plaintiff's evidence in determining whether Diapulse was safe and effective. Upon review of all of plaintiff's evidence, Dr. Hoover concluded that Diapulse was in fact safe and effective in the treatment of pain, swelling and edema, but only when used during the first forty-eight hours following an injury, in an inpatient or outpatient setting; in other words, he did not find it was safe and effective for treating chronic pain over time or when used by a patient at home. Habermann Decision 23.

Plaintiff submitted medical articles and testimony and questionnaires from expert physicians in support of its position. The ALJs, however, rejected the significance of this evidence for valid reasons. For example, ALJ Habermann cited Dr. Hoover's opinion that many of plaintiff's proffered studies in support of Diapulse were quite old, before more recent advances in treating pain and swelling, and focused on the use and efficacy of Diapulse in treating a variety of conditions, not just pain, swelling and edema. Habermann Decision 19, 30, 32. *See also* R. Vol. 1 and 2 (scientific literature supporting Diapulse).[20] ALJ Habermann also pointed out that,

[20] Even a cursory review of the medical literature submitted by plaintiff supports Dr. Hoover's characterization. *See, e.g.*, R. Vol. 1 at 12 (study involving children from 1975); *id.* at 71 (study involving dental surgery from 1971); *id*. at 83 (study involving migraine headaches); *id*. at 92 (study involving pelvic inflammation); *id*. at 125 (study involving alcohol-induced liver damage); *id*. at 180 (study involving childhood sinus conditions); *id*. at 297 (study involving

according to Dr. Hoover, the literature supporting the effectiveness of therapies similar to Diapulse in the treatment of edema all involved therapy rendered within seventy-two hours of an injury-producing trauma. Habermann Decision 30. ALJ Habermann noted as well that the studies plaintiff submitted failed to include research concerning the use of Diapulse in the home and by the elderly, an especially significant omission in light of the age of the population served by Medicare. *Id*. at 18, 23, 30. In addition, ALJ Habermann relied on Dr. Hoover's conclusion that most of the studies submitted by plaintiff were not conducted scientifically, in that they failed to describe the methods by which the patient-subjects were selected, did not employ uniform protocols for the strength, duration and number of treatments, and lacked information about control groups. *Id*. at 30. Finally, ALJ Habermann noted that plaintiff's experts offered only anecdotal, and sometimes conflicting, support for the use of Diapulse.[21] *Id*. at 21. In short, the ALJ considered plaintiff's evidence, but – for valid reasons explained in great detail in his decision – was not persuaded by it. Habermann Decision 33-35.

Plaintiff contends that ALJ Habermann also failed to credit the testimony of its experts that Diapulse treatments are generally accepted as reasonable and necessary. Pl. Mem. 16-17. Plaintiff proffered the testimony of nine medical experts and submitted questionnaires from five physicians who all indicated that they found the use of Diapulse therapy effective in treating a variety of conditions. Habermann Decision 12-17, 19-20. At least three of these witnesses testified that they believed Diapulse treatments were generally accepted by the medical community as an effective treatment for pain. *Id*. at 13, 20.

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rats); *id*. at 313 (same); *id*. at 346 (study involving monkeys).

[21] Moreover, it is not clear that plaintiff's experts had any personal knowledge about the safety and efficacy of the use of Diapulse at home. *See*, *e.g.*, R. Vol. at 675 (testimony of physician-witness who treated elderly patients in nursing homes with Diapulse).

The Medicare Program Integrity Manual states that "[a]cceptance by individual providers, or even a limited group of providers, normally does not indicate general acceptance by the medical community." *See* Habermann Decision 22; Medicare Program Integrity Manual, *available at* http://www.cms.hhs.gov/manuals/downloads/pim83c13.pdf. Although plaintiff's experts testified they used Diapulse and found it to be safe and effective in treating a variety of conditions, this testimony did not establish that Diapulse is generally accepted in the medical community. Rather, ALJ Habermann reasonably concluded that plaintiff's evidence reflected the individual preferences of its own witnesses, and not generally accepted medical practice.

Furthermore, the record before ALJ Habermann included substantial evidence supporting his conclusion that Diapulse treatments are *not* generally accepted. For example, Dr. Hoover testified to "an absence of support from the organizations that are higher on the generally accepted evidence pyramid," and identified the specific organizations he had in mind. Habermann Decision 18. In addition, ALJ Habermann submitted questionnaires to two physicians specializing in pain management who did not present testimony or submit questionnaires on plaintiff's behalf. One of the doctors reported that she had never used the Diapulse device and did not know of any doctors who had. *Id*. at 21. The other doctor also did not use the Diapulse device, but did use electric stimulators, and offered the view that electrical stimulation was generally accepted, but electromagnetic therapy such as Diapulse was not. *Id.* Even one of plaintiff's witnesses stated in a questionnaire that he believed that electrical stimulation was not generally accepted by the medical community as an effective treatment for pain. *Id.* at 20 (summary of testimony of Winkler). *See also* R. Vol. 14 at 672 (testimony at the hearing before ALJ Habermann of Sherman, one of plaintiff's witness-physicians, who stated merely that "some form of electrostimulation," and not necessarily electromagnetic therapy such as Diapulse, is

generally accepted). Viewed in its entirety, the record contains substantial evidence supporting ALJ Habermann's conclusion that the use of Diapulse in the home for the treatment of edema, pain and swelling is not generally accepted in the medical community.

2. ALJ Nisnewitz's Decision

The claims adjudicated by ALJ Nisnewitz involved the unsupervised home use of Diapulse treatments both to accelerate wound healing and alleviate pain. Nisnewitz Decision 4. With very few exceptions, these claims involved equipment rentals that took place after April 1, 2003. Pl. Mem. 6. As noted above, an NCD precluding coverage for the use of electromagnetic therapies such as Diapulse for treating wounds, and for any type of electrical stimulation used without supervision at home, was issued effective April 1, 2003. Although the NCD was modified effective July 1, 2004 to provide coverage for the use of electromagnetic therapies to treat wounds, the prohibition of coverage for unsupervised home use – of both ES and electromagnetic therapy – remained in effect.

ALJ Nisnewitz relied on these NCDs in reaching his decision to deny coverage for the Diapulse equipment rental claims before him. Plaintiff contends that he erred in three respects in doing so.

First, plaintiff contends that ALJ Nisnewitz misconstrued the NCDs when he applied their ban on home use when used to treat conditions other than open wounds. Pl. Mem. 20. It is clear from his decision, however, that ALJ Nisnewitz recognized that the coverage rules imposed by the NCDs applied only to treatment of wounds, and that the NCD in and of itself did not require that he deny coverage. Nisnewitz Decision 6 ("Payment for other uses of ES and electromagnetic therapy not otherwise specified for the treatment of wounds remain at the discretion of the carrier."). However, having considered the efficacy of Diapulse treatments when used to

ameliorate pain, ALJ Nisnewitz found the evidence of the benefits of Diapulse therapy for treatment of pain "less compelling" than the evidence that Diapulse treatments help wounds heal. Nisnewitz Decision 2. It was, therefore, reasonable for ALJ Nisnewitz to reject the idea of providing more generous coverage for Diapulse equipment when used to treat pain than when used to treat wounds.

Plaintiff's second argument is that ALJ Nisnewitz incorrectly applied the 2003 limitation on the unsupervised use of electrical stimulation to electromagnetic therapy. Pl. Mem. 21. The 2003 NCD, however, provides greater coverage for electrical stimulation than for electromagnetic therapy, and explicitly states that "[a]ny form of electromagnetic therapy for the treatment of chronic wounds will not be covered." Plaintiff's contention that the 2003 NCD somehow left the door open to coverage for home use of Diapulse equipment should therefore be rejected.[22]

Finally, plaintiff argues that it is improper to apply the 2003 and 2004 NCDs to equipment rentals that took place after their respective effective dates but as part of a course of therapy that began before April 1, 2003. Pl. Mem. 21-22. This argument should be rejected for the reasons already discussed above.

For all these reasons, I conclude that plaintiff's challenges to ALJ Nisnewitz's decisions are without merit and should be rejected.

3. Waiver of Liability

As noted above, an assignee of Medicare benefits that have been determined not to be reasonable or necessary may still be reimbursed if it did not know, and did not have reason to

[22] Moreover, when Diapulse requested CMS reconsider the 2003 NCD with respect to its denial of coverage for electromagnetic therapy, Diapulse argued that electromagnetic therapy is the same as electrical stimulation and should be covered to the same extent as ES. *See* 2003 Decision Memo at 7; Docket Entry 61-2 at 15. *See also* Nisnewitz Decision 8 (noting that Diapulse sought inclusion for electromagnetic therapy in the 2003 NCD and finding that studies have shown ES and electromagnetic therapies yield similar results).

know, that coverage would be denied. 42 U.S.C. § 1395pp(a); 42 C.F.R. § 411.406. In his decision, ALJ Habermann stated that "it has been the consistent policy of CMS not to cover the use of Diapulse therapy for ailments such as pain, swelling and edema." Habermann Decision 36. ALJ Habermann therefore concluded that Diapulse was not eligible for reimbursement pursuant to § 1395pp. *Id*.

The claims before ALJ Habermann involved fees for rental of the Diapulse device going as far back as 1995 and continuing through early 2003. *See* R. Vol. 12 at 4-7. It is not clear that Diapulse was on notice throughout this entire time period that its claims for rental of its equipment to treat non-open wounds, i.e., pain and edema, would not be covered. *See* R&R App. B. In fact, there is some evidence to the contrary. The first NCD limiting coverage was issued in 1997. As discussed above, however, implementation of the NCD was enjoined almost immediately thereafter. *Aitken*, 986 F. Supp. at 58. Moreover, ALJ Habermann himself determined that Diapulse therapy was covered for the treatment of wounds in 1997 and that the Diapulse device was safe and effective for home use in the treatment of wounds in 1999. Habermann Decision 2. It was not until June, 2001, when he issued his decision in Diapulse III, that ALJ Habermann denied coverage for rental of the device to treat non-open wounds. *Id.*; R. Vol. 18 at 2130. The first pertinent decision memo from CMS after implementation of the 1997 NCD was enjoined was not issued until July, 2002. In that decision memo, CMS indicated its intention to issue the 2003 NCD denying coverage for electromagnetic therapy for wounds. 2002 Decision Memo, *available at http://www.cms.hhs.gov/mcd/viewdecisionmemo.asp?id=27*. Although the skepticism about the efficacy of electromagnetic therapy in that decision memo should have alerted plaintiff, if it was not already aware, that its claims would not be covered, defendant has not identified earlier policy statements that should have caused plaintiff to know that coverage would be denied.

Moreover, it appears that Diapulse did receive Medicare reimbursement at times for rental of its device for use in the home for the treatment of pain, swelling and edema. For example, while plaintiff's appeal was pending before the MAC, Diapulse notified the MAC that six of the claims should be withdrawn because Diapulse had been paid. R. Vol. 12 at 9. In addition, Diapulse submitted a memorandum of law to the MAC and identified fully favorable decisions on claims involving the same type of medical conditions as were at issue before ALJ Habermann. R. Vol. 12 at 22 n.1.[23] If, as seems to be the case here, a beneficiary, provider, or supplier received conflicting information as to whether a claim would be reimbursed, the statutory waiver may apply. *See Yale-New Haven Hosp., Inc. v. Thompson*, 162 F. Supp. 2d 54, 68 (D. Conn. 2001) (denying a motion to dismiss a claim based on an ALJ's § 1395pp determination where provider alleged that it received Medicare payment for the devices during the time period for which the Secretary contended that the provider was on notice that the device would not be covered).

In his decision, ALJ Habermann did not identify which "CMS' notices, issuances and bulletins" gave Diapulse notice that its claims would not be covered. Habermann Decision 36. Thus, although he states in a conclusory fashion "that it was the consistent policy of CMS not to cover Diapulse for ailments such as pain, swelling, and edema," the support for that statement is not specified. *Id.* Similarly, ALJ Habermann states that there were LMRPs denying coverage for Diapulse when used in the home for the treatment of non-open wounds, Habermann Decision 27, but those policies, and in particular the dates on which the policies were issued, do not appear

[23] In the memorandum to the MAC, plaintiff does not state what medical conditions – open or non-open wounds – are the subject of its outstanding claims or the claims that were paid. Thus, it is not clear whether the prior favorable decisions are relevant to defendant's contention that plaintiff should have known its claims for treatment of non-open wounds would not be covered.

to be part of the record.[24]

For these reasons, there does not appear to be sufficient evidence specified in ALJ Habermann's decision to support his finding that plaintiff knew or should have known its claims would not be covered. *Cf. Willowood of Great Barrington, Inc. v. Sebelius*, 638 F. Supp. 2d 98 (D. Mass. 2009) (distinguishing *Yale-New Haven Hosp.*, 162 F. Supp. 2d at 54, and finding ample evidence to support the ALJ's determination that the provider knew the tests were not covered by Medicare); *Smith v. Thompson*, 210 F. Supp. 2d 994, 996-98 (N.D. Ill. 2002) (noting that the ALJ found that § 1395pp did not apply where ample evidence indicated that the beneficiary and his surgeon were aware that Medicare was not likely to pay for his surgery). Accordingly, I respectfully recommend remand to the ALJ with respect to the narrow question of whether the statutory waiver should apply throughout the entire time period for the claims at issue and, if so, greater specification of the bases upon which the ALJ concludes that plaintiff knew or should have known, prior to July, 2002 that its claims would not be covered.[25]

Conclusion

For all of the above-stated reasons, I respectfully recommend that plaintiff's motion for judgment on the pleadings be denied, and that defendant's motion for judgment on the pleadings be granted, except that a remand be issued with respect to the question of whether Diapulse is entitled to reimbursement pursuant to § 1395pp with respect to claims for rental fees incurred prior

[24] An LMRP is a Local Medical Review Policy promulgated by regional carriers in the absence of an NCD and "embodies the majority view of local health care providers regarding the medical necessity of a certain good or service." *Arruejo v. Thompson*, 2001 WL 1563699, at *4 (E.D.N.Y. July 3, 2001).

[25] Plaintiff does not raise the issue, but I note that substantial evidence supports ALJ Nisnewitz's conclusion that Diapulse knew or should have known that its claims would be denied. The claims before ALJ Nisnewitz were for rental of the device that post-dated the 2002 decisional memo. ALJ Nisnewitz cited the NCDs in support of his conclusion that Diapulse knew or should have known that the device would not be covered. Nisnewitz Decision 11. Thus, substantial evidence supports ALJ Nisnewitz's finding that the statutory waiver of liability does not apply with respect to plaintiff's claims before him.

to July 23, 2002, the date on which the CMS decision memo was issued.

Any objections to this Report and Recommendation must be filed within fourteen days and in any event no later than February 8, 2010. Failure to file objections within the specified time waives the right to appeal the District Court's Order. *See* 28 U.S.C. § 636(b)(1); FED. R. CIV. P. 6(a), 6(e), 72; *Small v. Sec'y of Health & Human Servs.*, 892 F.2d 15, 16 (2d Cir. 1989).

Dated: January 21, 2010
Brooklyn, New York

_____s/_____
Steven M. Gold
United States Magistrate Judge

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Appendix A

ALJ	Administrative Law Judge
APA	Administrative Procedures Act
CMS	Centers for Medicare & Medicaid Services (Formerly Health Care Financing Administration)
CMN	Certificate of Medical Necessity
DME	Durable Medical Equipment
DMERC	Durable Medical Equipment Regional Carriers
ES	Electrical Stimulation (Electrostimulation)
LMRP	Local Medical Review Policy
MAC	Medicare Appeals Council
MCM	Medicare Carriers Manual
MCPM	Medicare Claims Processing Manual
NCD	National Coverage Determination

Appendix B

			Citation
1987		FDA grants Diapulse clearance for post-operative treatment and pain	Def. Mem. App. B at 8
Pre - 4/1/97		Medicare coverage determinations for ES were made on a case-by-case basis.	Def. Mem. App. B at 6-7
4/1/97		NCD providing that Medicare would not reimburse for ES for wound healing (non-coverage NCD). Was enjoined by *Estate of Aitken v. Shalala*, 986 F. Supp. 57 (D. Mass. 1997). Policy of determining coverage thereafter continued on a case-by-case basis.	mentioned in Def. Mem. App. B at 7 and Nisnewitz Decision 5; Available on CMS website[26]
9/1/95 -6/30/03		Dates of provision of Diapulse DME considered in 2004 ALJ Habermann decisions. Claims related to treatment for pain and edema but not open wounds.	Compl. ¶ 14; Pl. Mem. 4
7/15/97		ALJ Habermann's Diapulse I decision, finding that Diapulse is covered for the treatment of open wounds	Habermann Decision 2
4/22/99		ALJ Habermann's Diapulse II decision, reaffirming his earlier conclusion that Diapulse is covered for the treatment of open wounds	Habermann Decision 2
6/28/01		ALJ Habermann's Diapulse III decision, finding that Diapulse is not covered for the treatment of non-open wounds	R. Vol. 18 at 2130
7/23/02	2002 Decision Memo	CMS Memo regarding its intent to issue NCD for coverage of ES for treatment of wounds; no coverage for electromagnetic therapy	Noted in Def. Mem. App. B at 7; Available on CMS website[27]
4/1/03	2003 NCD	NCD issued denying coverage for any form of electromagnetic therapy for treatment of chronic wounds	Def. Mem. App. C; R. Vol. 3 at 1020
12/17/03	2003 Decision Memo	CMS Memo concerning its intent to revise 2003 NCD to allow for coverage of electromagnetic treatment of certain wounds under supervision of health care professionals (i.e. not at home). Other uses of ES and electromagnetic therapy may be reimbursed on case by case basis.	Def. Mem. App. B
11/13-14/03 2/12-13/04		Hearings related to ALJ Habermann 2004 decisions. Each claim sought reimbursement for provision of Diapulse device for home use for treatment of a non-open wound during a specified period of time.	

[26] http://www.cms.hhs.gov/mcd/viewncd.asp?ncd_id=35-98&ncd_version=1&basket=ncd%3A35%2D98%3A1%3AElectrical+Stimulation+for+the+Treatment+of+Wounds

[27] http://www.cms.hhs.gov/mcd/viewdecisionmemo.asp?id=27

7/1/04	2004 NCD	ES and EMT allowed under certain conditions, and more specifically, for treatment of certain chronic ulcers that had not improved under other treatments when performed by health care professional.	Available on CMS website[28]
5/26/04; 6/22/04; 3/22/05	Habermann Decisions	ALJ Habermann's decisions denying reimbursement.	R. Vol. 13 at 336-73 (5/26/04); R. Vol. 12 at 278 (6/22/04); R. Vol. 12 at 31 (3/22/05)
9/7/05; 9/8/05 (2)	Nisnewitz Decisions	ALJ Nisnewitz decisions (each relating to similar claims regarding three different DMERCs).	R. Vol. 2 at 703-14 and R. Vol. 3 at 881-92 (9/7/05); R. Vol. 2 at 720 (9/8/05)
3/15/06; 3/16/06		Action of MAC denying requests for review of Habermann decisions. Action of MAC denying requests for review of Nisnewitz decision.	
5/12/06		Diapulse files in Federal Court	

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http://www.cms.hhs.gov/mcd/viewncd.asp?ncd_id=270.1&ncd_version=3&basket=ncd%3A270%2E1%3A3%3AElectrical+Stimulation+%28ES%29+and+Electromagnetic+Therapy+for+the+Treatment+of+Wounds